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Frank C. Eisenschenk, Ph.D., Patent Attorney

SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT

Examining Group 1617

Patent Application

Docket No. MET-037CXT Serial No. 09/900,364

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

AUG 3 1 2006

Examiner

Leonard M. Williams

Art Unit

1617

Applicants

Paul D. van Poelje, Mark D. Erion, Toshihiko Fujiwara

Serial No.

09/900,364

Filed

July 5, 2001

Conf. No.

7049

For

Combination of FBPase Inhibitors and Antidiabetic Agents Useful for the

Treatment of Diabetes

Mail Stop Amendment Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313

SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT UNDER 37 CFR §§1.97 AND 1.98

Sir:

In accordance with 37 CFR §1.56, the references listed on the attached form PTO/SB/08 are being brought to the attention of the Examiner for consideration in connection with the examination of the above-identified patent application. A copy of each cited reference is enclosed. However, Applicants have not submitted copies of the U.S. patents cited on attached Form PTO/SB/08 pursuant to 37 CFR 1.98(a)(2)(ii).

It is respectfully requested that the references cited on the attached form PTO/SB/08 be considered in the examination of the subject application and that their consideration be made of record.

This information is being submitted subsequent to the later of three months after the filing date of the present application or the mailing of the first Office Action on the merits, but before the mailing of a final action or the notice of allowance. Please charge the fee of \$180.00 to Deposit Account No. 19-0065.

Applicants respectfully assert that the substantive provisions of 37 CFR §§1.97 and 1.98 are met by the foregoing statement.

Respectfully submitted,

Frank C. Eisenschenk, Ph.D.

Patent Attorney

Registration No. 45,332

Phone No.: 352-375-8100 Fax No.: 352-372-5800

Address: P.O. Box 142950

Gainesville, FL 32614-2950

FCE/sl

Attachments: Form PTO/SB/08; copies of references cited therein.

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Substitute for form 1449A/PTO					Complete if Known		
INFORMA	TION DISCH	00			Application Number	09/900,364	
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SIAIEWE	INI DI APP	LICA	HIN I		First Named Inventor	Paul D. van Poelje	
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					Examiner Name	Leonard M. Williams	
Sheet	1	of		6	Attorney Docket Number	MET-037CXT	

U.S. PATENT DOCUMENTS								
Examiner Initials*	Cite No. 1	Document Number Number - Kind Code ² (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear			
	U1	US-4,968,790	11-06-1990	DeVries et al.	All			
	U2	US-5,728,704	03-17-1998	Mylari et al.	All			
	U3	US-4,278,791	07-14-1981	Botta et al.	All			
	U4	US-5,342,850	08-30-1994	Ohnota et al.	All			
	U5	US-6,147,101	11-14-2000	Maeda et al.	All			
	U6	US-						
	U7	US-						
	U8	US-						
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FOREIGN PATENT DOCUMENTS							
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Examiner Initials*	Cite No. 1	Country Code ³ - Number ⁴ - Kind Code ⁵ (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Where Relevant Passages or Relevant Figures Appear	T⁴	
	F1	EP 0354322	06-16-1989	American Cyanamid Company	All		
	F2	WO 99/45016	09-10-1999	Metabasis Therapeutics, Inc.	All		
	F3	WO 90/08155	07-26-1990	Board of Regents- University of Texas	All		
	F4	WO 90/10636	09-20-1990	Board of Regents- University of Texas	All		
	F5						
	F6						
	F7					<u> </u>	

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Signature	Cor	onsidered

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STATEMENT BY APPLICANT	First Named Inventor	Paul D. van Poelje	
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MET-037CXT Sheet of 6 **Attorney Docket Number**

		NON PATENT LITERATURE DOCUMENTS	
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	R1	AZEN, S.P. et al., "TRIPOD (TRoglitazone In the Prevention of Diabetes): A Randomized, Placebo-Controlled Trial of Troglitazone in Women with Prior Gestational Diabetes Mellitus," <i>Controlled Clinical Trials</i> , Vol. 19, Issue 2, Pages 217-231, Elsevier B.V. (April 1998).	
	R2	CHIASSON, JL. et al., "Acarbose for the prevention of Type 2 diabetes, hypertension and cardiovascular disease in subjects with impaired glucose tolerance: facts and interpretations concerning the critical analysis of the STOP-NIDDM Trial data," Diabetologia, 47: 969-975, Springer-Verlag (2004).	
	R3	DELORME, S. et al., "Acarbose in the prevention of cardiovascular disease in subjects with impaired glucose tolerance and type 2 diabetes mellitus," <i>Current Opinion in Pharmacology</i> , 5:184-189, Elsevier (2005).	
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	R6	ERION, M.D. <i>et al.</i> , "Computer-Assisted Scanning of Ligand Interactions: Analysis of the Fructose 1,6-Bisphosphatase-AMP Complex Using Free Energy Calculations" <i>J. Am. Chem. Soc.</i> 122:6114-6115 American Chemical Society (2000).	
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	R8	ERION, M.D. et al., "MB06322 (CS-917): A Potent and Selective Inhibitor of Fructose 1,6-Bisphosphatase for Controlling Gluconeogenesis in Type 2 Diabetes" <i>PNAS</i> 102(22): 7970-7975 (May 2005).	
	R9	FISHER, J.S. et al., "Glucose transport rate and glycogen synthase activity both limit skeletal muscle glycogen accumulation," <i>The American Journal of Physiology Endocrinol. Metab.</i> , Vol. 282, pp. E1214-E1221, American Physiological Society (June 2002).	
	R10	FUJIWARA, T. et al., "Suppression of Hepatic Gluconeogenesis in Long-Term Troglitazone Treated Diabetic KK and C57BL/KsJ-db/db Mice" Metabolism 44(4): 486-490 (April 1995).	

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Attorney Docket Number

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Application Number 09/900,364

Filing Date July 5, 2001

First Named Inventor Paul D. van Poelje

Group Art Unit 1617

Examiner Name Leonard M. Williams

		NON PATENT LITERATURE DOCUMENTS	
Examiner Initials*	Cite No. 1	Include name of the author (in CAPITAL LETTERS), title of the article, (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T²
		GIDH-JAIN, M. et al., "The Allosteric Site of Human Liver Fructose-1,6-Bisphosphatase" Journal of Biological Chemistry, 269(44): 27732-27738 The American Society for	
	R11	Biochemistry and Molecular Biology, Inc. (1994).	↓
	R12	HOLMAN, R.R. "Assessing the potential for α-glucosidase inhibitors in prediabetic states," <i>Diabetes Research and Clinical Practice</i> , Vol. 40, Supp. 1, Pages 21-25, Elsevier Ireland Ltd. (July 1998).	
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	R14	HULLEY, S. et al., "Randomized Trial of Estrogen Plus Progestin for Secondary Prevention of Coronary Heart Disease in Postmenopausal Women," J. of Am. Medical Assoc., Vol. 280, No. 7, pp. 605-613 (August 19, 1998).	
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	R16	MAGGS, D.G. et al., "Metabolic Effects of Troglitazone Monotherapy in Type 2 Diabetes Mellitus" Annals of Internal Medicine 128(3):176-185 American College of Physicians (February 1, 1998).	
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	R19	PICKAVANCE, L. et al., "The Development of Overt Diabetes in Young Zucker Diabetic Fatty (ZDF) Rats and the Effects of Chronic MCC-555 Treatment" British Journal of Pharmacology, 125: 767-770 Stockton Press (1998).	
	R20	POTTER, S.C. et al., "Effect of MB06322, a Potent and Selective Inhibitor of Fructose 1,6-Bisphosphatase, on Gluconeogenesis in the ZDF Rat as Assessed by the Deuterated Water Technique" <i>DIAEAZ</i> 52(2): A364, Journal of the American Diabetes Association Abstract No. 1516-P, American Diabetes Association (June 2004).	

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Sheet	4	of	6	Attorney Docket Number	MET-037CXT	

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	R21	POTTER, S.C. "Evidence Implicating Gluconeogenesis Inhibition as the Mechanism by Which MB06322 Lowers Blood Glucose In Vivo" <i>DIAEAZ</i> 52(2): A364, Journal of the American Diabetes Association Abstract No. 1517-P, American Diabetes Association (June 2004).	
	R22	PRISANT, L.M. "Preventing Type II Diabetes Mellitus," <i>J. Clin. Pharmacol.</i> , 44:406-413, American College of Clinical Pharmacology (2004).	
	R23	REDDY, M.R. and ERION, M.D. "Computer Aided Drug Design Strategies Used in the Discovery of Fructose 1,6-Bisphosphatase Inhibitors" <i>Current Pharmaceutical Design</i> 11: 283-294 Bentham Science Publishers Ltd. (2005).	
	R24	REDDY, K.R. et al., "Discovery of 2-Aminopyridine Inhibitors of FBPase" abstract for the 230 th National American Chemical Society (ACS) Meeting, Washington, DC, Aug./Sept. 2005, ACSMEDI Program and Abstract Book Archives, pp. 197-198, MEDI 323, obtained from http://oasys.acs.org/acs/230nm/medi/staff/separates.cgi 8/8/2005.	
	R25	REDDY, M.R. and ERION, M.D. "Fructose 1,6-Bisphosphatase: Use of Free Energy Calculations in the Design and Optimization of AMP Mimetics" <i>Free Energy Calculations in Rational Drug Design</i> , Chapter 14, 285-297 Springer-Verlag (2001).	
	R26	RIDDLE, M.C. "New Tactics for Type 2 Diabetes: Regimens Based on Intermediate-Acting Insulin Taken at Bedtime" <i>The Lancet</i> 192-195 (January 26, 1985).	
	R27	SATHYAPRAKASH, R. et al., "Preventing Diabetes by Treating Aspects of the Metabolic Syndrome," Current Diabetes Reports, 2:416-422, Current Science Inc. (2002).	
	R28	SCHEEN, A.J. and LEFEBVRE, P.J. "Oral Antidiabetic Agents A Guide to Selection" <i>Drugs</i> 55(2):225-236 Adis International Limited (February 1998).	
	R29	SREENAN, S. <i>et al.</i> , "Prevention of Hyperglycemia in the Zucker Diabetic Fatty Rat by Treatment with Metformin or Troglitazone" <i>Am. J. Physiol.</i> 271 (<i>Endorcinol. Metab.</i> 34): E742-E747 American Physiological Society (1996).	
	R30	SRIVASTVA, D.N. and FARQUHAR, D. "Bioreversible Phosphate Protective Groups: Synthesis and Stability of Model Acyloxymethyl Phosphates" <i>Bioorganic Chemistry</i> 12: 118-129 Academic Press, Inc. (1984).	

Examiner	 	Date	
Signature		Considered	

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Examiner Name Leonard M. Williams

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Sheet 5 of 6 Attorney Docket Number MET-037CXT

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		TORLONE, E. et al., "Improved Insulin Action and Glycemic Control After Long-Term			
	R31	Angiotensin-Converting Enzyme Inhibition in Subjects with Arterial Hypertension and Type II Diabetes" <i>Diabetes Care</i> 16(10):1347-1355 (October 1993).			
		TORRES, T. et al., "Inhibition of glycogen phosphorylase suppresses basal and glucagon-			
		induced glucose production and increases glucose uptake in the liver of conscious dogs"	1		
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	R32	Association (June 2003).			
		TRISCARI, J. et al., "Multiple Ascending Doses of CS-917, a Novel Fructose 1,6-			
		Bisphosphatase (FBPase) Inhibitor, in Subjects with Type 2 Diabetes Treated for 14 Days"			
		poster presented at The American Diabetes Association 66 th Scientific Session,			
	R33	Washington, DC (June 2006).			
	•	TURNBULL, A. et al., "Pharmacological inhibition of glycogen phosphorylase (GP) lowers			
	R34	plasma glucose in rat models of type 2 diabetes. (Integrated Physiology—Liver 1485-P)," Diabetes, Vol. 52 i6, p. A343, American Diabetes Association (June 2003).			
	R35	TURNER, R.C. <i>et al.</i> , "U.K. Prospective Diabetes Study 16: Overview of 6 Years' Therapy of Type II Diabetes, a Progressive Disease. (U.K. Prospective Diabetes Study Group)" <i>Diabetes</i> 44(11):1249(10) American Diabetes Association (Nov. 1995).			
	R36	UNGER, R. H. "How Obesity Causes Diabetes in Zucker Diabetic Fatty Rats" <i>Trends Endocrinol Metab</i> 7: 276-282 Elseveir Science Inc. (1998).			
	R37	VAN POELJE, P.D. et al., "Characterization of the Mechanism of Action and Antidiabetic Activity of MB06322, a Potent and Selective Inhibitor of Fructose 1,6-Bisphosphatase" DIAEAZ 52(2): A366, Journal of the American Diabetes Association Abstract No. 1523-P, American Diabetes Association (June 2004).			
. —		VAN POELJE, P.D., et al., "Comparative Metabolic Effects of a Novel Fructose 1,6-			
		Bisphosphatase Inhibitor and Metformin in the Female ZDF Rat", Abstracts of the 41 st			
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		VAN POELJE, P.D. et al., "Inhibition of Fructose 1,6-Bisphosphatase Reduces Excessive			
		Endogenous Glucose Production and Attenuates Hyperglycemia in Zucker Diabetic Fatty			
	R39	Rats" Diabetes 55:1747-1754, American Diabetes Association (June 2006).			

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(us	se as many sneets t	33 HEC	essary)	Examiner Name	Leonard M. Williams	
Sheet	6	of	6	Attorney Docket Number	MET-037CXT	

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	R40	VAN POELJE, P.D. et al., "MB06322 (CS-917) Lowers Blood Glucose in Rodents by Inhibiting Both Hepatic and Renal Gluconeogenesis" <i>DIAEAZ</i> 55(1): A137, Journal of the American Diabetes Association Abstract No. 575-P, American Diabetes Association (June 2006).			
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	R42	VAN POELJE, P.D. "MB06322, a Potent Inhibitor of Gluconeogenesis, Attenuates Hyperglycemia without Causing Weight Gain or Hypoglycemia in Female Zucker Diabetic Fatty Rats" <i>DIAEAZ</i> 54(1):A124, Journal of the American Diabetes Association Abstract No. 503-P, American Diabetes Association (June 2005).			
	R43	WALKER, J. et al., "Safety and Tolerability of Single Doses of CS-917, a Novel Gluconeogenesis Inhibitor, in Normal Male Volunteers" <i>DIAEAZ</i> 55(1): A463, Journal of the American Diabetes Association Abstract No. 2002-PO, American Diabetes Association (June 2006).			
	R44	WALKER, J. et al., "Safety, Tolerability and Pharmacodynamics of Multiple Doses of CS-917 in Normal Volunteers" <i>DIAEAZ</i> 55(1): A464, Journal of the American Diabetes Association Abstract No. 2003-PO, American Diabetes Association (June 2006).			
	R45	YOSHIDA, T. et al., "Comparison of Acute and Chronic Glucose-Lowering Effect of CS-917, a Fructose 1,6-Bisphosphatase (FBPase) Inhibitor, and Metformin in Rat Models of Type 2 Diabetes" poster presented at The American Diabetes Association 66 th Scientific Session, Washington, DC (June 2006).			
	R46	YOSHIDA, T. et al., "CS-917, a Fructose 1,6-Bisphosphatase Inhibitor, Has Glucose-Lowering Effects in Cynomolgus Monkeys and Improves Postprandial Hyperglycemia in Goto-Kakizaki (GK) Rats" <i>DIAEAZ</i> 54(1): A116-A117, Journal of the American Diabetes Association Abstract No. 472-P, American Diabetes Association (June 2005).			
	R47				
	R48				

Examiner	Date
Signature	Considered

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